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Remarks

Claims 6 through 8 and 12 through 30 remain pending in the application. The Office Action states that claims 8, 14, 17, 20, 26 and 29 are allowable if re-written in independent form, including all of the limitations of the base claims.

Regarding all of the rejections, the Examiner's rejections are based on guesswork. The proposed combinations, which do not meet the claimed limitations, would have an unpredictable hemodynamic effect if used on a human patient during CPR. Predicting hemodynamic behavior based on a change in a CPR device is certainly beyond the ordinary skill in the art, as indicated by the reluctance of the AHA to recommend changes to CPR procedures despite numerous studies on the hemodynamic effect of various chest compression techniques. (The AHA has not substantially changed its CPR recommendations in decades, despite an incredibly high death toll from heart attacks.) Since the rejections are based on guesses proposed by the Examiner and not based on facts available to anyone in the art of CPR, the Office Action has failed to state prima facie obviousness rejections.

Though the Examiner has made numerous conclusory statements that various modifications to the cited references would be mere matters of design choice, obvious provisions or "within design tolerances" (all of which are legally irrelevant to the obviousness inquiry), the Examiner has utterly failed to consider the hemodynamic effects of alterations in the application of pressure to the chest. The Examiner has provided no evidence whatsoever that the art contains any guidance whatsoever regarding the hemodynamic effects of such modifications. Thus, there appears to be no basis for the obviousness rejections other than the Examiner's own unique insights into hemodynamics.

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In addition, regarding all of the claims, had the claimed inventions been obvious then someone would have already publicly disclosed or sold the claimed inventions. The Examiner claims that Engstrom substantially shows the claimed invention, though to Applicants' knowledge nothing like Applicants' claimed invention has ever been disclosed or sold in the nearly 50 years since 1955. In fact, to Applicants' knowledge, Engstrom's invention was never sold or accepted by the market (providing an indication that Engstrom's device was not useful even as a respirator, much less as a device for performing chest compressions during CPR.) Given the tens of millions of deaths from heart attacks over the years and given the hundreds of thousands of highly trained doctors and medical professionals who have treated these victims, if the claimed inventions had been obvious "design choices," then someone would have already proposed the claimed inventions. However, no chest compression devices are on the market today except for those that perform chest compressions exactly according to current AHA guidelines. (For example, the Thumper® device performs point-compressions on a patient's chest according to AHA guidelines, much like a human hand might).

In addition, the Examiner appears to be operating under the misapprehension that there is a "convention" in the art of CPR devices. The only convention is the convention provided by the AHA, patents related to CPR devices, journal articles related to CPR and, possibly, the market. There is no market for CPR devices, except to a limited extent with respect to the Thumper® device - and the Thumper® device follows AHA guidelines for performing chest compressions. The AHA guidelines themselves are devoid of any reference to the claimed inventions, as are the published medical journals and CPR-related patents prior to Applicants' disclosure. Thus, any statement that one of ordinary skill in the art would find the proposed claim limitations within known conventions is, to Applicants' knowledge, without foundation and factually false.

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With respect to the rejections, the references cited by the Examiner to show that certain modifications are within "the realm of the ordinary artisan" or obvious "design tolerances" come from entirely different fields that have nothing to do with performing CPR. This practice is both without factual foundation and is legally inappropriate. To be both factually and legally relevant, the Examiner must provide references that are relevant to the art of devices for performing CPR and not to some nebulous notion of "the art." Engstrom, Sandman, Curlee and Huxley are all completely irrelevant to the pertinent art of CPR devices. Taking narrow statements from these references and applying them to a different art is without foundation and legally incorrect. This is especially true in the light that "conventions" in the art of CPR devices are well defined by the AHA and not by nebulous assertions proposed by the Examiner from entirely different fields. The "conventions" cited by the Examiner have never been accepted by the medical community, or put into practice and are therefore not conventions at all.

Now turning to the individual rejections, the Office Action rejects claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30 as obvious over Engstrom, Respirator, U.S. Patent 2,699,163 (Jan. 11, 1955) in view of Halperin, et al., Cardiopulmonary Resuscitation and Assisted Circulation System, U.S. Patent 4,928,674 (May 29, 1990) in view of Sandman, Anti-Shock Pressure Garment, U.S. Patent 4,355,632 (Oct. 26, 1982) under the assertion that Engstrom teaches a belt circumferentially disposed around the patient and a bladder attached to the belt, that Halperin shows a belt covering the length of the sternum of the chest, that Sandman that the bladder can be made from polyurethane-coated nylon fabric and that it would have been obvious to modify Engstrom (if not already inherent in Engstrom) to use a belt size to cover the length of the sternum as taught by Halperin to be able to adequately supply pressure to the chest and to use polyurethane-coated nylon fabric as taught by Sandman for a light-weight impermeable material.

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The Office Action ignores limitations of the claims and the proposed combination does not result in the claimed inventions. The proposed combination does not provide for the claimed feature that the bottom-chest panel and the top-belt panel form a radially extensible bellows. A bellows is a, "pleated expandable part, something constructed of a pleated material and, like a bellows, able to be expanded and contracted, e.g., the part inclosing the lenses on some cameras or photographic enlargers." Encarta World English Dictionary, 1999, p.159. Engstrom shows a bag, Halperin shows an inflatable vest and Sandman shows a pressure garment with a variety of bladders. None of these reference provide for a radially extensible bellows, as claimed, so the proposed combination does not result in the claimed inventions. Accordingly, the Office Action has failed to state a prima facie obviousness rejection against claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30.

Furthermore, there is no motivation in the art or in the references to modify the references to achieve the claimed radially extensible bellows. None of the references inherently disclose a radially extensible bellows, none suggest a radially extensible bellows and nothing in the prior art of CPR suggests such a device. Furthermore, the Office Action statement that "any conventional bag would have been an obvious provision" is both incorrect and completely without foundation. Substituting one kind of bladder or bag for another would have an unpredictable effect on the hemodynamics of the chest during compressions. Indeed, Applicants' research has shown that what appear to be small modifications in the design of a chest compression device can have a significant effect on hemodynamics, and thereby can have a significant effect on the effectiveness of chest compressions. Without some kind of technical support, the Examiner's statements are completely unfounded and are, to Applicants' knowledge, incorrect. Thus, there is no motivation to

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modify Engstrom and so claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30 are non-obvious.

In addition, the Office Action ignores the limitation that the belt is substantially circumferentially inextensible when fitted around the patient. Engstrom does not disclose or suggest this limitation. Engstrom also does not inherently disclose this limitation because it is not necessary that the belt be substantially radially inextensible; Engstrom's belt can still operate without this limitation. None of the other references disclose or suggest this limitation. Accordingly, the proposed combination does not result in the claimed invention and the Office Action has failed to state a prima facie obviousness rejection against claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30.

With regard to claims 7, 13, 19, 25 and 28, the Office Action ignores the limitation that the bottom-chest panel and the top-belt panel are made of nylon fabric *double coated* with polyurethane. Sandman does not show or suggest this limitation, the Office Action has provided no indication that double coating inflatable bladders was known in the prior art of CPR devices and the Office Action has provided no motivation to so modify Engstrom. Thus, the proposed combination does not result in the claimed invention and so the Office Action has failed to state a prima facie obviousness rejection.

In addition, the Office Action asserts that it would have been obvious to modify Engstrom as taught by Halperin to be able to "adequately supply pressure to the chest." The Examiner appears to be guessing as to what a person of ordinary skill in the art of CPR would believe would happen if Engstrom were modified as proposed, especially since Applicants (who have been in this field of research for over 20 years) did not know what would happen until they actually performed experiments. The Office Action statement is certainly lacking foundation without

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some pre-existing technical reference to support the Examiner's assertion. Moreover, the statement is vague since the Office Action provides no guidance as to what the term "adequate" means in the context of the claimed invention. At best, this statement adds nothing to the proposed modification of Engstrom since Engstrom is already able to adequately supply pressure to the chest to achieve his purpose. Likewise, Halperin provides adequate pressure to accomplish his purpose, as does Sandman. The Office Action statement is guesswork, represents impermissible hindsight and is meaningless vis-à-vis providing a motivation to combine the references. (The Office Action statement does not provide why one of ordinary skill would seek to combine the references.) Accordingly, no motivation has been provided to combine the references and so the Office Action has failed to state a prima facie obviousness rejection.

In addition, Engstrom is non-analogous art. Engstrom shows a device for performing artificial respiration that is not capable of performing CPR (as is claimed). Engstrom's design does not provide for this function, and given the financial and humanitarian benefits of assisting victims of cardiac arrest, he almost certainly would have mentioned this use for his belt had it been capable of performing chest compressions adequate for CPR. For similar reasons, Engstrom is not reasonably related to the problem to be solved, which is to create an improved device for performing CPR. Thus, Engstrom is non-analogous art and should be withdrawn as a reference. Accordingly, claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30 are non-obvious.

Sandman is also non-analogous art. Sandman shows a device for providing pressure to a patient in shock. Sandman's device is not in the same field as CPR and is not reasonably related to the problem to be solved. The fact that Sandman shows bladders may be made of polyurethane coated nylon is not reasonably related to the problem of creating a radially extensible bellows since he is

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creating his bladders for a purpose other than providing CPR to a patient. Thus, Sandman is non-analogous art and should be withdrawn as a reference. Accordingly, claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30 are non-obvious.

The Office Action rejects claims 15 and 16 as obvious over Engstrom in view of Halperin in view of Sandman and in view of Curlee, Compound Force Therapeutic Corset, U.S. Patent 4,682,588 (Jul. 28, 1987) under the assertion that Curlee shows bladders extending outside the width of the belt and that it would have been obvious to further modify Engstrom, Halperin and Sandman such that the bladder extends beyond the width of the belt as an obvious matter of design tolerances.

The Office Action has failed to provide a motivation to combine the references and thus has failed to state a prima facie obviousness rejection. Outdated maxims, such as design tolerances or design choice, have been replaced by the mandated test provided in Graham v. John Deere, which requires that the Examiner provide a motivation to combine or modify the references.

Furthermore, to Applicants' knowledge the Office Action statement is without foundation. To one of ordinary skill before Applicants' invention, extending the bladder beyond the width of the belt would have created an unpredictable hemodynamic effect during CPR. Thus, there is no reason to assert that extending the bladder beyond the width of the belt is an obvious matter of design tolerances. Instead, the claimed inventions provide for an advantage during CPR that was unappreciated in the prior art. Thus, claims 15 and 16 are non-obvious.

In addition, Curlee is non-analogous art. Curlee shows a back brace that uses air bladders to modify how the patient's back is supported. Curlee has nothing to do with devices for performing CPR. The disclosure in Curlee is also not reasonably related to the problem to be solved, which is providing an

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improved device for performing CPR. Thus, Curlee is non-analogous art and should be withdrawn as a reference. Accordingly, claims 15 and 16 are non-obvious.

The Office Action rejects claims 18 and 19 as obvious over Engstrom in view of Halperin in view of Sandman and in view of Huxley III, et al., Respirator Belt, U.S. Patent 2,899,955 (Aug. 18, 1959) under the assertion that Huxley teaches the convention of using a removable bladder and that it would have been obvious to further modify the combination to removably attach the bladder so as to be able to replace the bladder.

Claims 18 and 19 are non-obvious since the combination of Engstrom, Halperin and Sandman does not result in the claimed inventions. (The proposed combination does not show a radially extensible bellows or a circumferentially inextensible belt.) Thus, the Office Action has failed to state a prima facie obviousness rejection.

In addition, Huxley is non-analogous art. Huxley shows a respiration device disposed around a patient's abdomen and is thus unrelated to the claimed inventions. Huxley is also not reasonably related to the problem to be solved, which is to create an improved device for performing CPR. Thus, Huxley is non-analogous art and should be withdrawn as a reference. Accordingly, claims 18 and 19 are non-obvious.

In its response to arguments, the Office Action states that the dimensions of the belt are well within the realm of the artisan of ordinary skill. The Office Action states that Engstrom may inherently comprehend the limitation that the belt covers substantially the entire width of the chest and that Halperin is cited to teach such a convention.

The Office Action statements are factually and legally incorrect. Engstrom does not inherently disclose the claimed

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limitation. Inherent anticipation requires that the claimed element be *necessarily* present in the reference. Engstrom does not *necessarily* show a belt having a width covering substantially the entire superior-inferior length of the sternum because Engstrom could certainly perform the function of assisting respiration without covering the entire chest. Moreover, Halperin '674 does not discuss using a belt with his device; instead, he uses an inflatable vest. Thus, the Office Action has no reason to claim that Halperin shows that a belt should be of a certain width. Therefore, the proposed combination does not result in the claimed invention and so the Office Action has, again, failed to state a *prima facie* obviousness rejection.

Moreover, the Office Action statement that "such [dimensions are] a necessity if one is to provide complete pressure to the chest..." is clearly based on the hindsight guesswork of the Examiner. Applicants are unsure as to what "complete pressure to the chest" means, but assume here that the Examiner is referring to applying pressure to substantially the entire chest. Providing this kind of pressure to the chest (as suggested by Sandman to treat shock) has traditionally been, and remains, contra-indicated during CPR. The AHA guidelines call for pressure to be applied to a point on the sternum, not for complete pressure to the chest. Thus, the Office Action statement that "many prior art references teach this dimension [with respect to the belt]" is also factually incorrect. Indeed, prior art references *in the field of CPR* indicate that the opposite is true. See, for example, Lach et al., Resuscitation Method and Apparatus, U.S. Patent 4,770,164 (Sep. 13, 1988), who shows a CPR device having a narrow belt.

In its response to arguments the Office Action states that all bladders are formed of two panels with an air chamber formed therebetween. This statement is incorrect. Some bladders, such as many balloons, are continuous spheres or cylinders. The claimed bladder has a top and bottom panel in order to form a

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radially extensible bellows, a claimed feature that is neither disclosed nor suggested by the prior art or by any combination of the cited references. Accordingly, the claims are non-obvious.

In its response to arguments the Office Action states that one would look to Sandman for details regarding what materials to use to make a bladder and that any conventional bladder material would have been obvious in Engstrom. Applicants addressed this point with regard to the response to the rejection of claims 6, 7, 12, 13, 21 through 25, 27, 28 and 30.

Conclusion

In conclusion, the Office Action has taken a reference irrelevant to the art of CPR, made unfounded and incorrect assumptions of fact, supported the rejections with references irrelevant to the art of CPR or with a reference that does not mention the word "belt" (against claims that require both a belt and a radially extensible bellows) and then applied impermissible hindsight and factually unsupportable reasoning to form the claim rejections. Thus, the Office Action has failed to state prima facie obviousness rejections against claims that are clearly non-obvious to anyone of ordinary skill in the art of CPR devices.

Applicants request that the Examiner examine the claims according to legally appropriate standards, that any factual allegations be backed up by independent references, that each and every argument made herein be addressed in detail and that the claims be allowed.

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This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

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